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Effectiveness of Nicotine Patches in a Workplace Smoking Cessation Program: An Eleven-Month Follow-Up Study

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Abstract

Transdermal nicotine patches are widely prescribed as part of smoking cessation programs, but their efficacy beyond 6 months is not well established. We evaluated the efficacy of a 70-day treatment regimen among 75 subjects in an industrial setting where follow-up was conducted for 11 months. The median time free of cigarettes was 73 days, and the overall smoking abstinence rate was 9% after 11 months of follow-up. Smoking abstinence was significantly higher among those subjects who completed the full course of treatment than among those who did not (25 vs 6%, respectively). Smoking abstinence was also higher among subjects who started smoking after age 17 than among those who started at younger ages and was higher among male than female subjects. We conclude that transdermal nicotine patches are of limited efficacy in achieving long-term smoking cessation and that the relative costs and benefits of this treatment are not adequately specified.

Workplace policies restricting smoking have become increasingly prevalent over the past 10 years.¹ Many companies feel obligated to institute these policies because of increasing evidence implicating environmental tobacco smoke as a human carcinogen.² In addition, there is an economic incentive in helping workers to quit smoking. A recent study estimated that each smoker costs their company \$960 per year in excess illness costs.³ A variety of methods are available to assist employees who wish to quit smoking, including behavior modification, hypnosis, acupuncture, nicotine replacement therapy, and other pharmacologic therapy. Success rates have ranged from 4 to 80%, depending on the modality used and the length of follow-up.⁴

Nicotine gum, at adequate doses (4 mg/stick), has been shown to be effective in producing long-term smoking cessation when used with behavior modification.⁴ Use of nicotine leading to systemic absorption was first demonstrated in 1984.⁵ The results of 10 double-blind, placebo-controlled trials evaluating the effectiveness of nicotine patches have been summarized by McKenna and Cox.⁶ Most of the studies to date have shown a significant increase in cessation rates but have been limited to short-term follow-up. A more important measure of success is long-term follow-up after patch use has ceased. Three studies that have measured

success rates at 6 months or 12 months have shown success rates between 11 and 26%, where the outcome measure is complete abstinence from cigarettes.⁷⁻⁹

The purpose of our study was to examine the long-term efficacy of transdermal nicotine patches under circumstances of prescribing and follow-up that are routinely encountered in industry. The program was initiated simultaneously with a corporate policy to restrict smoking to designated outdoor locations.

Study Design and Subject Selection

Smokers were recruited on a volunteer basis from two plant sites of the DuPont Company. All interested persons were interviewed by the plant physician, a questionnaire was filled out, and informed consent was obtained. In addition to demographic characteristics, information was collected on smoking history, years of education, number of previous quit attempts, marital status, and level of confidence regarding continued abstinence at 6 months. A total of 75 subjects were enrolled between March and November 1992. There were 52 male and 23 female subjects ranging in age from 22 to 62 years. Forty-two subjects had 13 or more years of formal education and 33 had 12 years or less.

Nicotine replacement was provided by the use of the Nicoderm(R) patch (Marion Merrell Dow, Kansas City, MO). All patients were given the information book provided by the manufacturer along with instructions on the proper use and dosing of the nicotine patches. They were instructed to use one patch daily for 70 days, starting with 21 mg/day for 6 weeks, followed by 14 mg/day for 2 weeks then 7 mg/day for 2 weeks. Patches were provided to all participants at no cost either through the company medical clinic directly or through the medical insurance of the subjects. The subjects were invited to return to the medical department if they had any questions or concerns about the use of the patches but were not required to do so. Subjects were instructed to participate in a behavior modification program in addition to using the patches. An attempt was made to provide the program on site with a modest fee, which would be reimbursed if the employee attended all four sessions. However, none of the subjects was willing to participate in this program in conjunction with the patches.

Follow-up interviews were conducted periodically beginning in February 1993. All participants had at least one follow-up contact. Additional contacts were made to ascertain smoke-free and nicotine-free status in the subjects who continued to abstain. The outcome measure of interest was resumption of smoking as reported by the subject.

Statistical Methods

The study was designed to evaluate two related measures of success in quitting cigarettes. These were abstinence from cigarettes (smoking abstinence) and abstinence from nicotine (nicotine abstinence), ie the patches. Smoking

abstinence rates were calculated from the number of days elapsed from the time the subject stopped smoking until he or she either resumed smoking, was lost to follow-up, or the study ended, whichever came first. Under this measure, the time the subject used nicotine patches contributed to the time free of cigarettes. An alternative measure, the nicotine abstinence rate, was calculated from the number of days elapsed from the time the subject stopped using the patches until he or she either resumed smoking, was lost to follow-up, or the study ended, whichever came first. Under this measure, the time the subject used nicotine patches did not contribute to the time free of nicotine. This measure may be a more appropriate measure of success in quitting cigarettes, as it reflects the actual duration of abstinence from nicotine, whether it comes from cigarettes or nicotine patches.

Both the percentage of subjects who abstained from smoking (smoking abstinence rate) and the percentage of subjects who abstained from nicotine (nicotine abstinence rate) were calculated over the duration of follow-up using Kaplan-Meier survival methods.¹⁰ These rates were also calculated after stratifying on covariates (sex, education, number of nicotine patches used, level of confidence about quitting, age, race, and age at which the subject started smoking). The log-rank test was used to determine whether the quit rates differed between categories of covariates.¹⁰ The Statistical Analysis System (SAS)¹¹ was used to perform survival analyses.

Results

The participants were followed for 334 days after quitting cigarettes. At the end of the study, 2 of 75 subjects were known to be not smoking; smoking status was unknown for seven subjects, these individuals having been lost to follow-up (while still abstaining from cigarettes) at 70, 70, 105, 173, 189, 273, and 318 days after quitting cigarettes. The overall smoking abstinence rate was 73% at 1 month, 38% at 3 months, 16% at 6 months, and 9% at 11 months (Table 1). The median time free of cigarettes for the 75 subjects in the study was 73 days. The 14 subjects who completed the full prescription of 70 patches had a significantly higher smoking cessation rate throughout the duration of the study than did the 61 who did not complete the treatment ($P = .0021$). Among those who completed the full treatment of 70 patches, the smoking abstinence rate was 25%, compared with 6% of those subjects who did not complete the full regimen. Subjects who started smoking at age 17 or older had a significantly higher smoking abstinence rate (15% at 11 months) than subjects who started smoking before age 17 (3% at 11 $P = .0016$). Male subjects had a higher smoking cessation rate than did female subjects after 11 months (13 vs 0%, respectively), but this difference was not statistically significant. There was no statistically significant difference in smoking cessation rates according to years of education, level of confidence about quitting, age, or race.

The survival plot of smoking abstinence (Fig. 1) demonstrates a progressive decline in abstinence among all subjects over the first 9 months of the study, followed by a stable abstinence rate of 9% for the last 2 months. The survival plot for those 14 subjects who completed all 70 patches showed a progressive decline in abstinence over the first 6 months of the study, followed by a stable abstinence rate of 25% (based on six subjects) for the last 5 months. Of greater interest was the abstinence rate among those who did not complete the full treatment of 70 patches. In this group, the abstinence rate declined rapidly during the first 90 days after treatment began, then declined more slowly to 9 months, after which it remained stable at 6% (based on three subjects) for the remaining 2 months of the study.

The nicotine abstinence rate among all subjects was 48% at 1 month, 23% at 3 months, 11% at 6 months, and 6% at 11 months (Table 2). The median time free of nicotine for the 75 subjects in the study was 24 days. Subjects who completed the full prescription of 70 patches had a significantly higher nicotine abstinence rate throughout the duration of the study than did those who did not complete the treatment ($P = .003$). Among those who completed the 70 patches, the nicotine abstinence rate was 25% at 11 months, compared with 4% for subjects who did not complete the full treatment. Subjects who started smoking at age 17 or older had a greater nicotine abstinence rate (10% at 11 months) compared with subjects who started smoking before age 17 (0% success at 11 months; $P = .0034$). There was no significant difference in nicotine cessation rates between male and female subjects over the duration of the study, although male subjects had a higher cessation rate than female subjects after 9 months (9 vs 0%, respectively). There was no significant difference in nicotine abstinence rates according to years of education, level of confidence about quitting, age, or race.

The survival plot of nicotine abstinence (Fig. 2) demonstrates a progressive decline in nicotine abstinence among all subjects over the first 7 months, followed by a stable abstinence rate of 6% for the last 3 months. The survival plot for those who completed all 70 patches showed a progressive decline in nicotine abstinence over the first 6 months of the study, followed by a stable abstinence rate of 25% for the last 5 months. Among those who did not complete the full treatment of 70 patches, the abstinence rate declined rapidly during the first 60 days after treatment began, then declined more slowly to 7 months, after which it remained stable at 6% for the remaining 3 months of the study.

Discussion

Our study demonstrated limited success in smoking cessation by using transdermal nicotine patches. Our overall smoking abstinence rate at 6 months falls within the range reported in other published clinical trials.⁴ Although our prescription

for the nicotine patches included referral for behavioral intervention, subjects were unwilling to include this in their treatment plan. Our study did not include the use of a placebo treatment, and as a result it is not possible to determine whether nicotine-patch use produces better results than placebo administered by an identical regimen. Our study reflects the "real world" success rate with nicotine patches. Similar rates have been found in population-based surveys.¹² Results from the 1993 California Tobacco Survey found that the median time to relapse for patch users without additional assistance was only 15 days. In comparison with this rate, in the US civilian population 18 years and older, 5.7% of daily smokers quit smoking and maintained abstinence for at least 1 month during a 12-month period in 1990 to 1991, and an estimated 2.5% of US smokers quit smoking permanently each year during the period from 1974 to 1991.¹³

Few subjects (14 of 75) completed the full prescription of 70 patches, and the abstinence rate among those who did not finish the prescription was significantly worse than that among those who did. This observation, along with the failure of subjects to undergo behavioral intervention, indicates that patient compliance may be of extreme importance for this treatment. The recently published meta-analysis of 17 studies on the efficacy of nicotine patches¹⁴ found an overall abstinence rate of 22% (vs 9% for placebo) at 6 months. This study made an attempt to differentiate between high and low levels of behavioral counseling; however, they admit that the actual counseling information received by patients in the various studies could not be systematically examined. Even the studies that reported minimum counseling provided a much higher level of counseling and education than that which takes place in the real world. The poor nicotine abstinence rate among those who stopped using patches supports the interpretation that subjects stopped because they could no longer resist cigarettes, not because they had succeeded in quitting smoking. It also supports the conclusion that a prescription shorter than 70 days is less likely to succeed than is the full treatment. Only 3 of the 61 subjects who completed fewer than 70 patches remained off cigarettes at the end of the study. Our study also indicates that the subjects who are least likely to succeed in quitting smoking through the use of nicotine patches alone are those who began smoking before age 17, female more so than male subjects. Patch use alone appears to be of virtually no value in these groups.

It is possible that our subjects are not representative of the general population of smokers with respect to success in quitting smoking and therefore our results are not applicable to smokers in other segments of the population. However, a number of facts argue against this. The study population included all who volunteered to try nicotine patches. Employees were not excluded; neither were there rewards for participation or for successful completion of the

prescription. In addition, our results indicate that the subjects who believed themselves to be highly motivated to quit smoking did not achieve significantly better success than those who were less motivated. Thus, we believe this study is representative of employed populations and that our results are likely to be generalizable to other populations who are offered nicotine patches as part of an employer-supported smoking cessation program.

Typical prices for Nicoderm(R) patches in southeastern Michigan currently range between \$23.50 and \$29.50 per week. Thus, the total cost of 10 weeks of treatment is between \$235 and \$295 per patient, and the pharmaceutical cost per successful participant (9 of 75 participants) in our study is estimated to be between \$1958 and \$2458. The costs of professional time and behavioral modification therapy were not estimated and would add appreciably to this figure. Comparison of these costs with the estimated \$960 per year in excess illness costs per smoker indicates that the use of nicotine patches may be economically justified in spite of the relatively low success rate of this therapy. However, given that the payback period for the pharmaceutical costs alone exceeds 2 years, long-term studies to assess the efficacy of nicotine patches over periods of at least 2 years (and in comparison with no treatment) are necessary to more accurately estimate the long-term costs and benefits of this therapy.

References

1. Rigotti NA. Trends in the adoption of smoking restrictions in public places and worksites. NY State J Med. 1989;89:19-26. ExternalResolverBasic Bibliographic Links
2. Repace JL, Lowrey AH. A quantitative estimate of nonsmokers' lung cancer risk from passive smoking. Environ Int. 1985;11:3-22. ExternalResolverBasic
3. Bertera RL. The effects of behavioral risks on absenteeism and health care costs in the workplace. J Occup Med. 1991;33:1119-1124. ExternalResolverBasic Request Permissions Bibliographic Links
4. Tonnesen P, Fryd V, Hansen M, et al. Effect of nicotine chewing gum in combination with group counseling on the cessation of smoking. N Engl J Med. 1988;318:15-18. ExternalResolverBasic Bibliographic Links
5. Rose JE, Jarvik ME, Rose KD. Transdermal administration of nicotine. Drug Alcohol Depend. 1984;13:209-213. ExternalResolverBasic Bibliographic Links
6. McKenna JP, Cox JL. Transdermal nicotine replacement and smoking cessation. Am Fam Physician. 1992;45:2591-2601. ExternalResolverBasic

7. Tonneson P, Norregaard J, Simonsen, et al. A double-blind trial of a 16 hour transdermal nicotine patch in smoking cessation. N Engl J Med. 1991;325:311-315.
ExternalResolverBasic
8. Daughton DM, Heatley SA, Prendergrast JJ, et al. Effect of transdermal nicotine delivery as an adjunct to low intervention smoking cessation therapy. A randomized, placebo-controlled, double-blind study. Arch Intern Med. 1991;151:749-752.
ExternalResolverBasic Bibliographic Links
9. Transdermal Nicotine Study Group. Transdermal nicotine for smoking cessation. JAMA. 1991;266:3133-3138. ExternalResolverBasic
10. Lee ET. Statistical Methods for Survival Data Analysis, 2nd ed. New York: Wiley; 1992:66-130.
11. Sas Institute Inc. SAS/STAT User's Guide, Version 6, 4th ed., Vol. 2. Cary NC: SAS Institute Inc.; 1989:1027-1069.
12. Pierce JP, Gilpin E, Farkas AJ. Nicotine patch use in the general population: results from the 1993 California Tobacco Survey. J Natl Cancer Inst. 1995;87:87-93.
13. Centers for Disease Control. Smoking cessation during previous year among adults-United States, 1990 and 1991. MMWR CDC Surveill Summ. 1993;42:504-507.
ExternalResolverBasic
14. Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation: a meta-analysis. JAMA. 1994;271:1940-1947.
ExternalResolverBasic Bibliographic Links
How Sweet It Is

Citizens of Belgium and Luxembourg eat 11.15 pounds of cocoa per person per year, putting them No. 1 in the world chocoholic rankings. Switzerland ranked second in the list published by the International Cocoa Organization, with the Swiss consuming 10.45 pounds per person annually. The United States was ninth at 4.94 pounds. [In] consumption of chocolate candy, Switzerland led the world with 21.38 pounds per person per year. The United States ranked eleventh with 10.8 pounds.

From Schogol M. Food Watch. Philadelphia Inquirer, September 20, 1995, p. F1.



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TABLE 1

	Mean abstinence (days)	Median abstinence (days)	Abstinence rate (%)				Log-rank χ^2	P
			1 month	3 months	6 months	11 months		
Overall	94	73	73	38	16	9	NA	NA
Patch Use								
70	141	137	100	75	38	25	9.49	.0021
1-69	78	61	67	28	11	4		
Age started smoking								
17+	118	84	86	47	24	11	9.9	.0016
≤16	59	36	56	25	3	3		
Sex								
Male	98	63	69	38	21	9	.54	.46
Female	82	75	83	35	20	0		
Years education								
13+	89	73	76	36	13	9	.01	.92
≤12	96	71	70	39	20	5		
Level of Confidence								
5-7	99	75	76	40	18	7	.97	.33
1-4	71	36	65	29	12	6		
Age								
≤40	85	71	73	36	12	4	.46	.50
41+	100	74	74	39	20	9		
Race								
Nonwhite	128	84	87	48	24	8	1.98	.16
White	82	64	70	35	12	7		

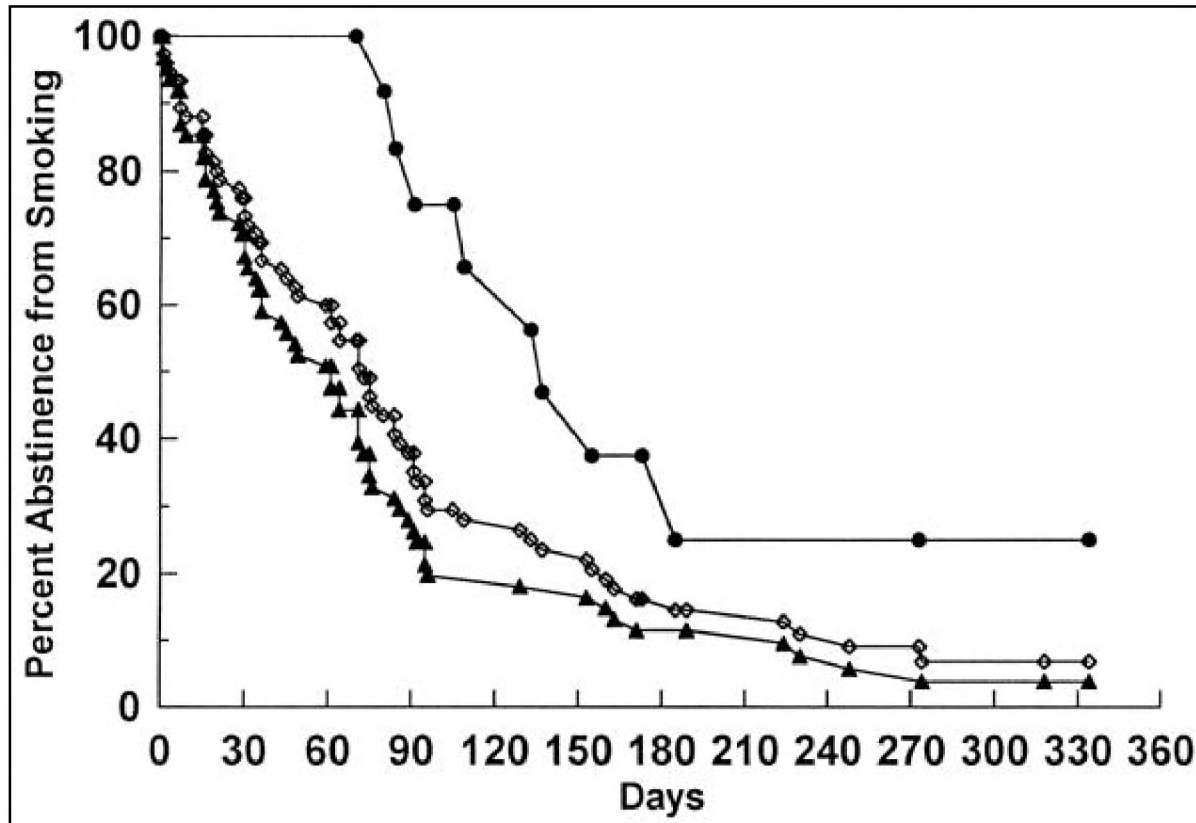
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TABLE 1 . Smoking Abstinence

Fig. 1



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Fig. 1 . Smoking abstinence rates during 11 months of follow-up after quitting cigarettes. [diamond operator], all subjects; [black up pointing small triangle], subjects who used 1 to 69 patches; *, subjects who used 70 patches.

TABLE 2

	Mean abstinence (days)	Median abstinence (days)	Abstinence rate (%)				Log-rank χ^2	P
			1 month	3 months	6 months	11 months		
Overall	56	24	48	23	11	6	NA	NA
Patch Use								
70	71	67	75	38	25	25	4.73	.0296
1-69	48	15	43	23	9	4		
Age started smoking								
17+	75	41	56	33	17	10	8.56	.0034
≤16	32	12	38	9	0	0		

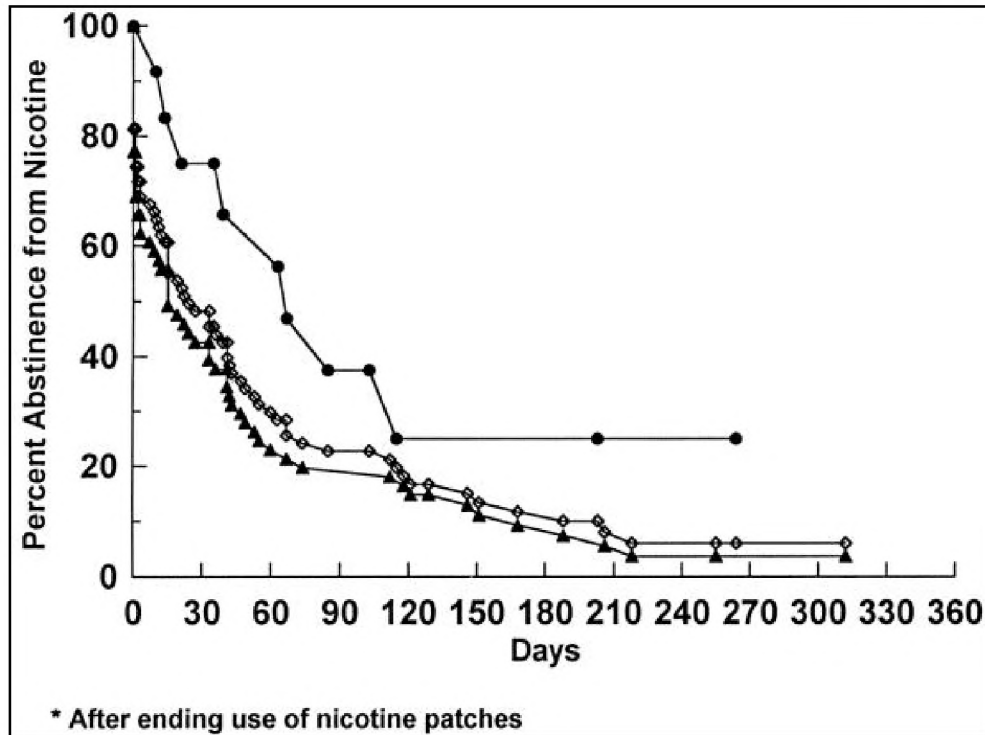
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TABLE 2 . Nicotine Abstinence

Fig. 2



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Fig. 2 . Nicotine abstinence rates during 11 months of follow-up after quitting cigarettes. [diamond operator] White diamonds, all subjects; [black up pointing small triangle], subjects who used 1 to 69 patches; *, subjects who used 70 patches.